OCT 2 5 2011

510(k) Summary

NAME OF SPONSOR:

Ortho Development Corporation
12187 South Business Park Drive
Draper, Utah 84020

510(k) CONTACT:

Tom Haueter
Regulatory Affairs Manager
Telephone: (801) 553-9991
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Email: thaueter@orthodevelopment.com

DATE PREPARED: June 30, 2011

PROPRIETARY NAME: Vusion®OS

COMMON NAME: Intervertebral Body Fusion Device

CLASSIFICATION: 21 CFR888.3080, Intervertebral Body Fusion Device.

DEVICE PRODUCT CODE: MAX

PREDICATE DEVICES:

Vusion® TS, PS, and CS Partial VBR (K062666)
Ortho Development Corp

Vu™ ePOD& Vu™ LPOD (K082712)
Theken Spine, LLC

Ardis® Spacer (K073202)
Abbott Spine Inc.

Device Description

Vusion® OS consists of implants with various widths, lengths, heights, and degrees of lordosis. The implant is provided in widths from 9mm to 11mm, lengths from 20mm to 35mm, and heights ranging from 7mm to 16mm.The implants are made from Polyetheretherketone (PEEK Optima LT1, ASTM F2026) and contain tantalum markers (tantalum per ASTM F560), which allow radiographic confirmation of proper positioning. The implants have ridged teeth that resist rotation and migration, and holes to accommodate bone graft. The implant geometry includes a bulleted nose, fixation teeth on the superior and inferior surfaces, side windows, a graft window passing between the superior and inferior surfaces, and an insertion hole and rails for implant placement control. The implant is sold non-sterile.Vusion® OS is implanted using a standard or oblique PLIF (Posterior Lumbar Interbody Fusion) approach and is intended to be used singly or in pairs with supplemental fixation.

Indications for Use

Vusion® OS is indicated for use as an intervertebral body fusion device at one or two contiguous levels (L2-S1) in skeletally mature patients with degenerative disc disease (DDD) with up to Grade 1 spondylolisthesis or retrolisthesis at the involved level(s). DDD is defined as back pain of discogenic origin with degeneration of the disc confirmed by history and radiographic studies. These patients may have had a previous non-fusion spinal surgery at the involved spinal level(s). Vusion® OS is to be used with supplemental fixation and autogenous bone graft. Patients should have at least six months of non-operative treatment prior to treatment.

Basis for SubstantialEquivalence

Vusion® OSwas evaluated in accordance with FDA Documents, *Class II Special Controls; Guidance Document: Intervertebral Fusion Device, June 12, 2007,* and has been found to meet criteria defined therein.

The following non-clinical tests were conducted:

- Static and dynamic compression testing per ASTM F2077.
- Static torsion testing per ASTM F2077.
- Subsidence testing per ASTM F2267.
- Expulsion testing per ASTM Draft Standard F-04.25.02.02.

Conclusions

Based on similarities in intended use, design, materials, manufacturing methods, and packaging, Vusion® OS has demonstrated that it is substantially equivalent to the previously

cleared predicate devices. Mechanical test results demonstrate that the proposed Vusion® OS is substantially equivalent to the predicate devices.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Room –WO66-G609
Silver Spring, MD 20993-0002

OCT 2 5 2011

Ortho Development Corporation
% Mr. Tom Haueter
12187 South Business Park Drive
Draper, Utah 84020

Re: K111965
Trade/Device Name: Vusion® OS
Regulation Number: 21 CFR 888.3080
Regulation Name: Intervertebral body fusion device
Regulatory Class: Class II
Product Code: MAX
Dated: September 21, 2011
Received: October 11, 2011

Dear Mr. Haueter:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you; however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must

comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please go to http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

for Mark N. Melkerson
Director
Division of Surgical, Orthopedic
and Restorative Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

K111965

Indications for Use

510(k) Number (if known): K111965

Device Name: Ortho Development **Vusion® OS**

Indications for Use:

Vusion® OS is indicated for use as an interbody fusion device at one or two contiguous levels (L2-S1) in skeletally mature patients with degenerative disc disease (DDD) with up to Grade 1 spondylolisthesis or retrolisthesis at the involved level(s). DDD is defined as back pain of discogenic origin with degeneration of the disc confirmed by history and radiographic studies. These patients may have had a previous non-fusion spinal surgery at the involved spinal level(s). Vusion® OS is to be used with supplemental fixation and autogenous bone graft. Patients should have at least six months of non-operative treatment prior to treatment.

Prescription Use ___X_____ AND/OR Over-The-Counter Use _____
(Part 21 CFR 801 Subpart D) (Part 21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Division Sign-Off
Office of In Vitro Diagnostic Device
Evaluation and Safety

510(k) K111965